



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-372]

Exempt Chemical Preparations Under the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Order with opportunity for comment.

SUMMARY: The applications for exempt chemical preparations received by the Drug Enforcement Administration (DEA) between August 30, 2021, and March 31, 2022, as listed below, were accepted for filing and have been approved or denied as indicated.

DATES: Interested persons may file written comments on this order in accordance with 21 CFR 1308.23(e). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. eastern time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-372” on all correspondence, including any attachments.

Electronic comments: DEA encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a comment tracking number, your comment has been successfully submitted and there is no need to resubmit the same comment.

Paper comments: Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-8201.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business

information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at <http://www.regulations.gov> for easy reference.

Legal Authority

Section 201 of the Controlled Substances Act (CSA) (21 U.S.C. 811) authorizes the Attorney General, by regulation, to exempt from certain provisions of the CSA certain compounds, mixtures, or preparations containing a controlled substance, if he finds that such compounds, mixtures, or preparations meet the requirements detailed in 21 U.S.C. 811(g)(3)(B).¹ The Drug Enforcement Administration (DEA) regulations at 21 CFR 1308.23 and 1308.24 further detail the criteria by which the DEA Assistant Administrator may exempt a chemical preparation or mixture from certain provisions of the CSA. The Assistant Administrator may, pursuant to 21 CFR 1308.23(f), modify or revoke the criteria by which exemptions are granted and modify the scope of exemptions at any time.

Exempt Chemical Preparation Applications Submitted Between August 30, 2021, and March 31, 2022

DEA received applications between August 30, 2021, and March 31, 2022,

¹ This authority has been delegated from the Attorney General to the DEA Administrator by 28 CFR 0.100, and subsequently redelegated to the Deputy Assistant Administrator pursuant to 28 CFR 0.104 and section 7 of the appendix to subpart R of part 0.

requesting exempt chemical preparation status detailed in 21 CFR 1308.23. Pursuant to the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23, the Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart I below is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or animal and either: (1) contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse; or (2) contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration that the preparation or mixture does not present any potential for abuse and, if the preparation or mixture contains a narcotic controlled substance, is formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have ill effects, if abused, and so that the narcotic substance cannot in practice be removed.

Accordingly, pursuant to 21 U.S.C. 811(g)(3)(B), 21 CFR 1308.23, and 21 CFR 1308.24, the Assistant Administrator has determined that each of the chemical preparations or mixtures generally described in Chart I below and specifically described in the application materials received by DEA is exempt, to the extent described in 21 CFR 1308.24, from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003, and 1004 (21 U.S.C. 822-823, 825-829, and 952-954) of the CSA, and 21 CFR 1301.74, as of the date that was provided in the approval letters to the individual requesters.

Scope of Approval

The exemptions are applicable only to the precise preparation or mixture described in the application submitted to DEA in the form(s) listed in this order and only for those above mentioned sections of the CSA and the CFR. In accordance with 21 CFR

1308.24(h), any change in the quantitative or qualitative composition of the preparation or mixture, or change in the trade name or other designation of the preparation or mixture after the date of application requires a new application. The requirements set forth in 21 CFR 1308.24(b)-(e) apply to the exempted materials. In accordance with 21 CFR 1308.24(g), DEA may prescribe requirements other than those set forth in 21 CFR 1308.24(b)-(e) on a case-by-case basis for materials exempted in bulk quantities.

Accordingly, in order to limit opportunity for diversion from the larger bulk quantities, DEA has determined that each of the exempted bulk products listed in this order may only be used in-house by the manufacturer, and may not be distributed for any purpose, or transported to other facilities.

Additional exempt chemical preparation requests received between August 30, 2021, and March 31, 2022, and not otherwise referenced in this order, may remain under consideration until DEA receives additional information required, pursuant to 21 CFR 1308.23(d), as detailed in separate correspondence to individual requesters. DEA's order on such requests will be communicated to the public in a future *Federal Register* publication.

DEA also notes that these exemptions are limited to exemption from only those sections of the CSA and the CFR that are specifically identified in 21 CFR 1308.24(a). All other requirements of the CSA and the CFR apply, including registration as an importer as required by 21 U.S.C. 957.

Chart I

Supplier	Product Name	Form	Application Date
Aalto Scientific, Ltd.	Unassayed Chemistry Base Level 1	Glass or plastic bottle or flask: 1mL-100 mL; 100mL-500mL; 500mL-1L	3/28/2022
Aalto Scientific, Ltd.	Unassayed Chemistry Base Level 2	Glass or plastic bottle or flask: 1mL-100 mL; 100mL-500mL; 500mL-1L	3/28/2022

RTI International	2023 UT-02	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-03	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-05	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-06	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-07	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-08	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-09	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-10	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-11	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-12	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-13	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-14	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UT-15	HDPE Bottle: 50 mL	3/30/2022
RTI International	2023 UTCO-01	HDPE Bottle: 40 mL	3/30/2022
RTI International	2023 ZE-01	Vial: 5 mL	3/30/2022
RTI International	2023 ZE-02	Vial: 5 mL	3/30/2022
RTI International	2023 ZE-03	Vial: 5 mL	3/30/2022
RTI International	2023 ZE-04	Vial: 5 mL	3/30/2022
RTI International	2023 ZE-05	Vial: 5 mL	3/30/2022
RTI International	2023 ZE-06	Vial: 5 mL	3/30/2022
RTI International	2023-OFD-09	Vial: 2 mL	3/30/2022
RTI International	Sample 1 Matrix: Urine	HDPE tubes: 5 mL	3/7/2022
RTI International	Sample 2 Matrix: Urine	HDPE tubes: 5 mL	3/7/2022
RTI International	Sample 3 Matrix: Plasma	HDPE tubes: 5 mL	3/7/2022
RTI International	Sample 4 Matrix: Urine	HDPE tubes: 5 mL	3/7/2022
RTI International	Sample 6 Matrix: Whole Blood	HDPE tubes: 5 mL	3/7/2022
Thermo Fisher Scientific	Cascadion SM Antiepileptics Internal Standard	Box: 6 vials, 29 mL each	3/24/2022

The Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart II below is not consistent with the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23. Accordingly, the Assistant Administrator has determined that the chemical preparations or mixtures generally described in Chart II below and specifically described in the application materials received by DEA, are not exempt from application of any part of the CSA or from application of any part of the

CFR, with regard to the requested exemption pursuant to 21 CFR 1308.23, as of the date that was provided in the determination letters to the individual requesters.

Chart II

Supplier	Product Name	Form	Application Date
Chemtos, LLC	ANPP (1 mg/mL in acetonitrile)	Amber ampule: 1mL	3/14/2022
CPI International	Custom Hormone Mix, 9-072, 1000 mg/L, 6 x 1 ml	1 Package; 6 x 1 mL amber ampules	1/14/2022
LGC Clinical Diagnostics, Inc.	TDM1 ab WrkBlk - Level 5	Volumetric flask: 200 - 8000 mL	3/21/2022
LGC Clinical Diagnostics, Inc.	TDM1 au WrkBlk - Level 5	Volumetric flask: 200 - 8000 mL	3/21/2022
LGC Clinical Diagnostics, Inc.	TDM1 bc WrkBlk - Level 5	Volumetric flask: 200 - 8000 mL	3/21/2022
LGC Clinical Diagnostics, Inc.	TDM1 db WrkBlk - Level 5	Volumetric flask: 200 - 8000 mL	3/21/2022
LGC Clinical Diagnostics, Inc.	TDM1 ri GentC Set WrkBlk - Level 5	Volumetric flask: 200 - 8000 mL	3/21/2022
LGC Clinical Diagnostics, Inc.	TDM1 ri TDM Set WrkBlk - Level 5	Volumetric flask: 200 - 8000 mL	3/21/2022
LGC Clinical Diagnostics, Inc.	TDM1 vt Set WrkBlk - Level 5	Volumetric flask: 200 - 8000 mL	3/21/2022
LGC Clinical Diagnostics, Inc.	Validate TDM Phenobarbital Stock	Plastic vial: 150 mL	3/21/2022

Opportunity for Comment

Pursuant to 21 CFR 1308.23(e), any interested person may submit written comments on or objections to any chemical preparation in this order that has been approved or denied as exempt. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Assistant Administrator will immediately suspend the effectiveness of any applicable part of this order until she may reconsider the application in light of the comments and objections filed. Thereafter, the Assistant Administrator shall reinstate, revoke, or amend his original order as she determines appropriate.

Approved Exempt Chemical Preparations are Posted on the DEA's Web site

A list of all current exemptions, including those listed in this order, is available on the DEA's Web site at
http://www.DEAdiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf. The dates

of applications of all current exemptions are posted for easy reference.

Kristi O'Malley,
Assistant Administrator.

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